UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,233	06/27/2003	Imtiaz Chaudry	0040964-0002	8210

826 7590 10/17/2006

ALSTON & BIRD LLP
BANK OF AMERICA PLAZA
101 SOUTH TRYON STREET, SUITE 4000
CHARLOTTE, NC 28280-4000

EXAMINER	
HAGHIGHATIAN, MINA	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/609,233	CHAUDRY, IMTIAZ	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-7,10-30 and 32-69* is/are pending in the application.

4a) Of the above claim(s) *6,7,10,11,17-20,22-24,33,35-37 and 41-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5,12-16,21,25-30,32,34,38-40 and 51-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/02/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Amendments, Remarks and IDS filed on 08/02/06. Claims 1, 27, 38 and 51 have been amended and claims 3-4, 8-9 and 31 have been cancelled. Accordingly, of the pending claims, claims 6-7, 10-11, 17-20, 22-24, 33, 35-37 and 41-50 are withdrawn and claims 1-2, 5, 12-16, 21, 25-30, 32, 34, 38-40 and 51-69 are under examination.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 1-2, 5, 12-16, 21, 25-30, 32, 34, 38-40 and 51-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al (5,554,610) in view of Schmehl et al (US 20060002992 A1) or alternatively in view of Azria et al (5,759,565) or alternatively in view of Schwarz (US 20010031738).

Williams teaches a **method for the treatment** of **pulmonary hypertension** comprising administering to a mammal an effective amount of a vasodilator. The formulations can treat primary and secondary pulmonary hypertensions (col. 2, lines 1-6). The administration is preferably **through inhalation**. **Unit doses** comprising 0.01 to 50 mg and preferably from 0.1 to 10 mg of the compound are normally administered one to 4 times a day. The compositions are prepared by admixture and can be in a solution or **suspension** form (col. 2, lines 16-48, 60-67). One preferred composition

comprises in an **aqueous suspension** form, additives such as suspending agents, preservatives, carriers and **buffers**. The said agents include **propylene glycol**, **ethyl alcohol,** etc. The compositions for administration to the respiratory tract are presented as **snuff** or an aerosol or solution for a **nebulizer** or as a microfine powder for insufflation, alone or in combination with an inert carrier. In other preparations, such as for parenteral administration, the fluid unit dose forms are prepared containing the compound and a **sterile** vehicle, undergo **filter sterilization** and filled into a vial. The compositions are typically accompanied by written or printed directions for use (see col. 3, lines 1-66).

Williams also discloses that suitable vasodilators include **calcium channel blockers** such as **nifedipine** (col. 4, lines 20-21). A particularly favored pharmaceutically acceptable composition is an inhalation composition, suitably in unit dosage form (col. 4, lines 37-40). Williams lacks disclosure on pH levels and isotonicity of the formulations.

Schmehl et al teaches atomizable liposomes and their use for the pulmonary administration of active substances. It is disclosed that the current form of therapy for pulmonary hypertension is the inhalation of vasodilators such as prostacyclin and derivatives thereof (see [0009]). The formulations are comparable to an isotonic solution (see [0018]) and preferably have a pH of 7.4 (see [0021]).

Azria et al teach compositions for nasal administration. It is disclosed that "generally, for **nasal** administration a mildly acid pH will be preferred. Preferably the compositions of the invention have a **pH of from about 3 to 5**, most preferably 3.5 to 4.5. Adjustment of the pH is achieved by addition of an appropriate acid, such as hydrochloric acid. The compositions of the invention should also possess an appropriate isotonicity and viscosity" (see col. 4, lines 15-25). The formulations are filtered using a 0.2 μm filter (see col. 8, lines 30-38).

Schwarz teaches a method of treating pulmonary hypertension by inhalation. It is discloses that the aerosol **suspensions** can be aerosolized by a metered dose inhaler ([0049]) or with a pressure-driven **aerosol nebulizer** or an **ultrasonic nebulizer**. The suitable carrier is typically water and most preferably **sterile** water, and preferably made **isotonic**. Optional preservatives, **pH-adjusting agents**, **buffering** agents and surfactants are included (see [0041] and [0051]). The doses of the active compounds may be provided as **one or several prepackaged units** (see [0059]). It is also disclosed that suitable formulations comprise **citrate** or bis/tri buffer (**pH 6**) (see [0045]).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have implemented teachings of Schmehl et al on atomizable formulations or alternatively the teachings of Azria et al on nasal administration of formulations or Schwarz on inhalation of formulation for treating pulmonary

hypertension, with the general teachings and formulations of Williams et al with a reasonable expectations of successfully preparing efficient and easy to use formulations that treat pulmonary hypertension in patients. In other words Williams et al are teaching the inhalation of vasodilators for treating pulmonary hypertension. However, they are silent with regards to suitable pH levels and isotonicity of the formulations. It is well known in the art that mucosal membranes tolerate certain isotonicity and pH levels. It is also well known in the art that pH levels are adjustable by use of acids, bases or buffers. Williams et al disclose the use of buffers for their formulations. Schmehl et al, Azria et al and Schwarz are support that it is known in the art that an isotonic formulation having pH levels of 3-8 are suitable for inhalation and nasal administrations. Thus it is clearly shown that all limitations of the instant claims are met by Williams in view of Schmhel, Azria, Schwarz or knowledge generally available to one of ordinary skill in the art.

Response to Arguments

Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mina Haghighatian
October 05, 2006

Johann Richter, Ph.D. Esq.
Supervisory Patent Examiner
Technology Center 1600